GTP Bioways
CDMO
Continuum for biologics

Case Study

Use of an innovative viral inactivation method for a complex recombinant protein to be used as vaccine for COVID-19

The Challenge

All commonly employed viral inactivation methods proved to be incompatible with the protein of interest. Consequently, the project necessitated the exploration of a novel approach to ensure continued progress towards GMP production.

BIOLOGICS

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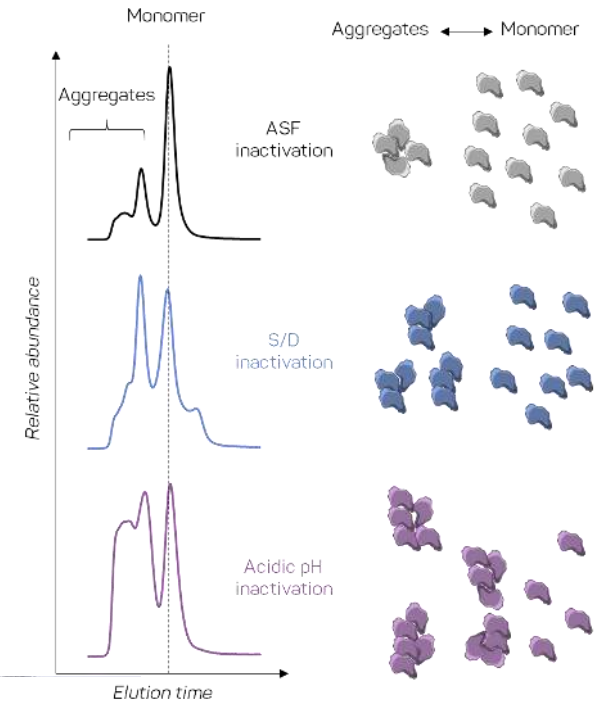
Context & Challenge

Our client required the development of a second-generation COVID-19 vaccine using a technology that specifically enables dendritic cells (DCs) to present viral antigens. This strategy induces a strong and lasting immune response. The molecule of interest needs to be ambivalent: It has to bind DCs and carries several antigens. This complexity results in a multi-subunits molecule of high molecular weight (>250 kDa). This kind of molecules is often prone to chemical degradation and/or aggregation.

One mandatory phase when manufacturing biologics using mammalian cells is virus removal. This is classically achieved by implementing dedicated steps in the purification process such as viral inactivation and nanofiltration. Two main modes of viral inactivation currently predominate: Incubation at acidic pH for a couple of hours, or treatment with a combination of solvent and detergent (S/D). Both strategies expose proteins to harsh conditions. When developing the purification process for this specific protein, we found out that it aggregated in either of the two environments (acidic pH and S/D).

GTP Bioways' Solution

How to move forward? Returning to molecular design would mean a major setback for the project which could not suffer such a delay in the context of a pandemic. Instead, we tried out alternative virus inactivation protocols and found inspiration in published reports (see McCue *et al.*, 2014, *Biotechnol Prog.*, 30(1):108-12, for instance). We could successfully inactivate viruses using a combination of arginine and a synergistic factor without any detectable protein aggregation.



> “What usually works for classical antibodies is often not suitable for recombinant proteins and especially complex molecules. We must constantly remain open-minded to prevent or get out of difficult situations.”
>
> Patricia Boutonnet, Downstream Process Expert

Our client’s success

The project has then moved forward to manufacturing after a phase of process optimization. The efficiency of the whole purification strategy to remove potential viruses has to be validated according to International Council for Harmonisation (ICH) guidelines. This step is performed by our trusted partner Texcell which has more than 30 years of experience in safety testing of biological products.

Although there are inherent uncertainties in the development of innovative therapies, have your cGMP material on time for clinical studies should not be one. With GTP Bioways, you can be guaranteed that your project will receive the utmost care and attention, from start to finish.

Don't miss this chance to unlock your biologics manufacturing potential.

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or call +33 5 82 28 09 40 to speak directly with one of our knowledgeable experts today!

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